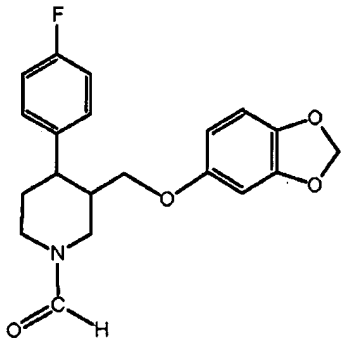
Amendments to the Claims

The following listing of claims replaces all prior versions and listings of claims in this application:

Listing of Claims:

1-22 (cancelled).

23 (original). A process for determining the stability or purity of a paroxetine substance or composition, which comprises assaying a paroxetine substance or composition for the presence of an N-formyl paroxetine compound of formula (1):



24 (original). The process according to claim 23, wherein said paroxetine substance or composition is a paroxetine pharmaceutical composition.

25 (original). The process according to claim 24, wherein said paroxetine pharmaceutical composition has been stored for at least three months before carrying out said assaying step.

26 (amended). The process according to claim 24, wherein said ~~assay~~ assaying comprises the use of thin layer chromatography or high pressure liquid chromatography.

27 (original). A process, which comprises

forming a production lot of paroxetine pharmaceutical solid dosage forms wherein each dosage form comprises paroxetine or a pharmaceutically acceptable salt thereof and at least one pharmaceutically acceptable excipient;

removing a sample of said paroxetine pharmaceutical solid dosage forms from said production lot;

assaying said sample for the presence and/or amount of N-formyl paroxetine; and

selling or releasing said production lot if said sample passes said assay with respect to the presence or amount of N-formyl paroxetine.

28 (original). The process according to claim 27, wherein said sample passes said assaying step if the amount of N-formyl paroxetine does not exceed a predetermined upper limit.

29 (amended). The process according to claim [27] 28, wherein said predetermined upper limit is the detection limit of said assaying step.

30 (original). The process according to claim 27, wherein said paroxetine or pharmaceutically acceptable salt is selected from the group consisting of paroxetine, paroxetine hydrochloride, paroxetine maleate, paroxetine acetate, and paroxetine methane sulfonate.

31 (new). The process according to claim 28, wherein said predetermined upper limit is 0.01% of N-formyl paroxetine based on the weight of the paroxetine compound.

32 (new). The process according to claim 28, wherein said predetermined upper limit is within the range of 0.01% to 0.1% of N-formyl paroxetine based on the weight of the paroxetine compound.

33 (new). The process according to claim 28, wherein said predetermined upper limit is 0.05% of N-formyl paroxetine based on the weight of the paroxetine compound.

34 (new). The process according to claim 28, wherein said predetermined upper limit is 0.1% of N-formyl paroxetine based on the weight of the paroxetine compound.

35 (new). The process according to claim 28, wherein said predetermined upper limit is 0.2% of N-formyl paroxetine based on the weight of the paroxetine compound.

36 (new). A process for manufacturing paroxetine hydrochloride tablets, which comprises

forming a production lot of at least 100,000 paroxetine pharmaceutical tablets, wherein said tablets comprise 1 to 50 mg of paroxetine hydrochloride and at least one pharmaceutically acceptable excipient;

removing a sample of said paroxetine hydrochloride tablets from said production lot;

testing said sample for compliance with a manufacturing specification, said testing including assaying said sample for the presence and/or amount of N-formyl paroxetine and said manufacturing specification including a predetermined upper limit

for the amount of N-formyl paroxetine; and

selling or releasing said production lot if said sample meets said manufacturing specification.

37 (new). The process according to claim 36, wherein said predetermined upper limit for the amount of N-formyl paroxetine is the detection limit of said assaying.

38 (new). The process according to claim 36, wherein said predetermined upper limit for the amount of N-formyl paroxetine is within the range of 0.01% to 0.2% based on the weight of the paroxetine.

39 (new). The process according to claim 38, wherein said predetermined upper limit for the amount of N-formyl paroxetine is within the range of 0.01% to 0.1% based on the weight of the paroxetine.

40 (new). The process according to claim 36, wherein said predetermined upper limit for the amount of N-formyl paroxetine is 0.1% based on the weight of the paroxetine.

41 (new). The process according to claim 36, wherein said forming of said production lot comprises blending paroxetine hydrochloride and at least one pharmaceutically acceptable excipient and compressing into said tablets.

42 (new). The process according to claim 41, wherein said predetermined upper limit for the amount of N-formyl paroxetine is within the range of 0.01% to 0.1% based on the weight of the paroxetine.

43 (new). The process according to claim 36, wherein said forming of said production lot comprises tabletting by direct compression.

44 (new). The process according to claim 43, wherein said predetermined upper limit for the amount of N-formyl paroxetine is within the range of 0.01% to 0.1% based on the weight of the paroxetine.